IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/ FENFLURAMINE/DEXFENFLURAMINE) PRODUCTS LIABILITY LITIGATION	)	MDL NO. 1203
THIS DOCUMENT RELATE TO:	)	
SHEILA BROWN, et al.	)	
v.	)	CIVIL ACTION NO. 99-20593
AMERICAN HOME PRODUCTS CORPORATION	)	2:16 MD 1203

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO. 9517

Bartle, J. November 22, 2019

Julie J. Panoussi ("Ms. Panoussi" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,[1] seeks benefits from the AHP Settlement Trust ("Trust"). Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support her claim for Matrix Compensation Benefits ("Matrix Benefits").[2]

1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation. In 2009, Pfizer, Inc. acquired Wyeth.

2. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"). They generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD").

(continued . . .)

To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

In August, 2016, claimant submitted a completed Green Form to the Trust signed by her attesting physician, Duncan Salmon, M.D. Based on an echocardiogram dated April 24, 2015,[3]

(continued . . .)
See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these Diet Drugs.

3. Because claimant's April 24, 2015 echocardiogram was performed after the end of the Screening Period, claimant relied on an echocardiogram dated November 6, 2011 to establish her eligibility to receive Matrix Benefits. The Screening Period ended on January 3, 2003 for echocardiograms performed outside of the Trust's Screening Program and on July 3, 2003 for echocardiograms performed in the Trust's Screening Program. See Settlement Agreement § I.49.

Dr. Salmon attested in Part II of Ms. Panoussi's Green Form that claimant suffered from severe mitral regurgitation and had surgery to repair or replace the aortic and/or mitral valve(s) following the use of Pondimin® and/or Redux™.[4] Based on such findings, claimant would be entitled to Matrix A-1, Level III benefits[5] in the amount of $297,859.[6]

Dr. Salmon also attested that Ms. Panoussi did not suffer from mitral annular calcification. Specifically, he said, "The mitral posterior leaflet is thickened—there is no annular calcification (see that surgeon corroborates this). The annulus is well seen in apical 2-chamber view." Under the Settlement Agreement, the presence of mitral annular

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4. Dr. Salmon also attested that claimant suffered from an abnormal left atrial dimension, an ejection fraction of between 35% and 39%, New York Heart Association Functional Class III symptoms, and severe regurgitation and the presence of ACC/AHA Class I indication for surgery to repair or replace the mitral valve where such surgery was not performed. These conditions are not at issue in this claim.

5. Under the Settlement Agreement, a claimant is entitled to Level III benefits if he suffered from "left sided valvular heart disease requiring . . . [s]urgery to repair or replace the aortic and/or mitral valve(s) following the use of Pondimin® and/or Redux™." See id. § IV.B.2.c.(3)(a).

6. Ms. Panoussi previously was paid Matrix A-1, Level II benefits in the amount of $473,032. According to the Trust, if entitled to A-1, Level III benefits, Ms. Panoussi would be entitled to Matrix Benefits in the amount of $770,891. The amount at issue, therefore, is the difference between the Matrix A-1, Level II benefits already paid and the amount of Matrix A-1, Level III benefits.

calcification requires the payment of reduced Matrix Benefits for a claim based on damage to the mitral valve. See id. § IV.B.2.d.(2)(c)ii)d). As the Trust does not contest claimant's entitlement to Level III benefits, the only issue before us is whether claimant is entitled to payment on Matrix A-1 or Matrix B-1.

In October, 2016, the Trust forwarded the claim for review by Zuyue Wang, M.D., one of its auditing cardiologists. In audit, Dr. Wang concluded that there was no reasonable medical basis for finding that claimant did not have mitral annular calcification. Pursuant to Court Approved Procedure No. 11, the Consensus Expert Panel[7] subsequently reviewed Ms. Panoussi's claim. The Consensus Expert Panel did not recommend re-audit of Ms. Panoussi's claim.

Based on the auditing cardiologist's findings, the Trust issued a post-audit determination that Ms. Panoussi was entitled only to Matrix B-1, Level III benefits. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit

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7. The Consensus Expert Panel consists of three cardiologists, one designated by each of Class Counsel, the Trust, and Wyeth. See Pretrial Order ("PTO") No. 6100 (Mar. 31, 2005). We approved creation of the Consensus Expert Panel to "monitor the performance of the Auditing Cardiologists and to develop procedures for quality assurance in the Audit of Claims for Matrix Compensation Benefits." Id.

Rules"), claimant contested this adverse determination.[8] In contest, Ms. Panoussi argued that there was a reasonable basis for finding that mitral annular calcification was not present on the April 24, 2015 echocardiogram. In support, Ms. Panoussi submitted an affidavit from Dr. Salmon that stated that "the April 24, 2015 echocardiogram does not show Ms. Panoussi to have mitral annular calcification" because (1) his visual review of the April 24, 2015 echocardiogram confirms "that there was slight or mild thickening of the mitral valve region, not calcification" and that the leaflet is thickened but the annulus, a different structure, is not calcified; (2) the surgeon who performed Ms. Panoussi's mitral valve repair "specifically noted in his operative findings that 'there was not annular calcification"; (3) the physician interpreting Ms. Panoussi's April 28, 2015 echocardiogram did not find mitral annular calcification, which is particularly important because the April 28, 2015 echocardiogram was a transesophageal echocardiogram and therefore provides "the best views of the left atrium and mitral valve"; and (4) Ms. Panoussi underwent

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8. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in Pretrial Order ("PTO") No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Ms. Panoussi's claim.

mitral valve repair, rather than replacement, surgery and "calcification of the mitral annulus renders mitral valve repair difficult and replacement surgery is typically performed in cases involving mitral annular calcification."

Although not required to do so, the Trust forwarded the claim to the auditing cardiologist for a second review. Dr. Wang submitted a declaration in which she again concluded that there was no reasonable medical basis for finding that Ms. Panoussi did not have mitral annular calcification. Specifically, Dr. Wang stated:

> 10. As requested by the Trust, I again reviewed all the claim materials reviewed in audit as well as Claimant's Contest Materials, including the affidavit of Dr. Duncan Salmon and the Echocardiogram report of a transesophageal echocardiogram dated April 28, 2015.
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> 11. Based on my review, I confirm my finding at audit that there is no reasonable medical basis for the Attesting Physician's finding that Claimant did not have [mitral annular calcification]. Upon review in contest, I again reviewed the entire April 24, 2015 EOA and identified the presence of moderate [mitral annular calcification]. [Mitral annular calcification] is clearly seen on this study. The April 24, 2015 study is on a disk. I took screen shots from both the opening and closing of the mitral valve on this transthoracic study which clearly show moderate mitral annular calcification prior to Ms. Panoussi's mitral valve repair. See, Exhibits B & C annexed hereto. (For ease of reference, I have labeled and marked with arrows the depiction of the posterior mitral

valve leaflet and the [mitral annular calcification].) The bright linear echo density is located at the mitral annulus where the posterior mitral leaflet attaches. Contrary to Dr. Salmon, this clearly meets criteria for the proper diagnosis of mitral annular calcification.

12. I disagree with Dr. Salmon's assertion that had [mitral annular calcification] been present, the patient would have had mitral valve replacement surgery rather than mitral valve repair. It is not true that patients with mitral annular calcification are more likely to undergo mitral valve replacement. Most surgical mitral valve repairs require an annuloplasty ring to be sewn to the annulus, which although difficult if there is calcium deposit, is neither uncommon nor beyond the ability of a skilled surgeon. I have often provided echo guidance to many mitral valve repairs in patients with even severe [mitral annular calcification]. Calcium which appears on echo in a transthoracic study may be buried in the annulus and may not be seen by a surgeon. Accordingly, I did not defer to the surgeon's finding. Further, Dr. Salmon fails to acknowledge that [mitral annular calcification] can best be seen on a transthoracic echocardiogram study as opposed to a transesophageal study.

13. I disagree with Dr. Salmon's suggestion that 4/28/2015 Echocardiogram Report reference to mild thickening of the mitral valve and silence as to the presence or absence of [mitral annular calcification] should trump the proper diagnosis of [mitral annular calcification] clearly shown on Ms. Panoussi's 4/24/2015 study. No copy of the 4/28/2015 study itself was submitted with either the claim or the Contest Materials in this matter.

14. For the foregoing reasons, there is no reasonable medical basis to

> conclude that Ms. Panoussi did not have [mitral annular calcification].

The Trust then issued a final post-audit determination again determining that Ms. Panoussi was entitled only to Matrix B-1, Level III benefits. Claimant disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807, Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why Ms. Panoussi's claim should be paid. On April 12, 2018, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 9499 (Apr. 12, 2018).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on July 3, 2018. Under the Audit Rules, it is within the Special Master's discretion to appoint a Technical Advisor[9] to review claims after the Trust and

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9. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge--helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. United States, 863 F.2d 149, 158 (1st Cir. 1988). In a case such as this, where conflicting expert opinions exist, it is within the discretion of the court to appoint a Technical Advisor to aid it in resolving technical issues. Id.

claimant have had the opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned a Technical Advisor, Gary J. Vigilante, M.D., F.A.C.C., to review the documents submitted by the Trust and claimant and to prepare a report for the court. The Show Cause Record and Technical Advisor Report are now before the court for final determination. See id. Rule 35.

The issue presented for resolution of this claim is whether claimant has met her burden of proving that there is a reasonable medical basis for finding that she did not have mitral annular calcification. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for this finding, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for this finding, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

In support of her claim, Ms. Panoussi repeats the arguments that she made in contest. In addition, she contends that there is a reasonable medical basis for Dr. Salmon's representation because he relied "on multiple sources of medical evidence and provides a common sense contextual framework for evaluating the issue presented in this claim" while the Trust's

auditing cardiologist relied only on the April 24, 2015 echocardiogram.

In response, the Trust argues that the Settlement Agreement requires denial of the claim because the auditing cardiologist determined that there was no reasonable medical basis for the Green Form representation at issue. According to the Trust, claimant would prefer simply to ignore the auditing cardiologist's specific finding of the presence of mitral annular calcification. The Trust also points out that we previously have rejected arguments that the amount of calcification must rise to the level of clinical significance and that mitral annular calcification under the Settlement Agreement refers to the pathological condition rather than the mere presence of any calcification in the mitral annulus.

The Technical Advisor, Dr. Vigilante, reviewed claimant's echocardiogram and concluded that there was no reasonable medical basis for finding that Ms. Panoussi did not have mitral annular calcification. Specifically, Dr. Vigilante stated, in pertinent part:

> I reviewed the DVD of the Claimant's echocardiogram of attestation. This study was dated April 24, 2015. The name "Julie Panoussi" was noted on the study. This was an excellent quality study with all of the usual views. The Nyquist limit was appropriately set at between 61.6 and 63.1 cm per second in the apical views. I reviewed all 105 images/loops. This study

> demonstrated obvious calcification of the posterolateral mitral annulus manifested by significant increased thickness and refractoriness of echoes classic for calcification. This was seen in all views in which the mitral valve was identified. The posterolateral mitral annular calcification was best noted in loop 4 in the parasternal long axis view, loop 23 in the parasternal short axis view, loop 38 in the apical four chamber view, and loop 52 in the apical two chamber view. There was significant thickening of the anterior mitral leaflet and restriction of the posterior mitral leaflet. . . .
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> In response to Question 1, there is no reasonable medical basis for the Attesting Physician's answer to Green Form Question D.9. That is, the echocardiogram of attestation dated April 24, 2015 demonstrates classic mitral annular calcification. An echocardiographer could not reasonably conclude that mitral annular calcification was not present on the study even taking into account inter-reader variability. Of note, the presence of mitral annular calcification on this study was documented by the original interpreting cardiologist.

After reviewing the entire show cause record, we find that Ms. Panoussi's arguments are without merit. As noted previously, the Settlement Agreement provides that the presence of mitral annular calcification requires the payment of reduced Matrix Benefits. See Settlement Agreement § IV.B.2.d.(2)(c)(ii)(d). We disagree with Ms. Pannousi that there is a reasonable medical basis for finding that her

April 24, 2015 echocardiogram does not demonstrate mitral annular calcification.

Dr. Wang and Dr. Vigilante each reviewed claimant's April 24, 2015 echocardiogram and concluded that it demonstrated mitral annular calcification. Specifically, Dr. Wang noted that she "identified moderate [mitral annular calcification]" and that "[mitral annular calcification] is clearly seen on this study." She attached two screen shots that "clearly show moderate mitral annular calcification prior to Ms. Panoussi's mitral valve repair." Dr. Vigilante also concluded, with respect to the April 24, 2015 echocardiogram, that "[t]his study demonstrated obvious calcification of the posterolateral mitral annulus manifested by significant increased thickness and refractoriness of echoes classic for calcification." Dr. Vigilante noted that "posterolateral mitral annular calcification was best noted in loop 4 in the paresternal long axis view, loop 23 in the parasternal short axis view, loop 38 in the apical four chamber view, and loop 52 in the apical two chamber view." Notably, the cardiologist who initially interpreted claimant's echocardiogram noted "[t]here is mild mitral annular calcification." Neither Dr. Wang nor Dr. Vigilante simply deferred to the findings of claimant's

surgeon in light of these specific findings, which claimant does not adequately dispute.[10]

In fact, Dr. Salmon concedes that the echocardiogram shows thickening of the mitral leaflet but says that it does not show annular calcification. We previously have rejected the argument that a claim should not be reduced because the level of mitral annular calcification is not significant. The Settlement Agreement specifically provides that a claimant will receive reduced Matrix Benefits for a mitral valve claim if he or she is diagnosed by echocardiogram with mitral annular calcification. See Settlement Agreement § IV.B.2.d.(2)(c)(ii)(d). The Settlement Agreement provides that the presence of mitral annular calcification, regardless of level, requires the payment of reduced Matrix Benefits. Unlike some of the other factors that reduce a claim to Matrix B-1, any presence of mitral annular calcification, regardless of the amount, places the claim on Matrix B-1. Compare Settlement Agreement § IV.B.2.d.(2)(c)(ii)(d) with Settlement Agreement § IV.B.2.d.(2)(c)(i)(d) ("Aortic root dilatation > 5.0 cm").

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10. Although claimant contends that her April 28, 2015 echocardiogram supports the conclusion that she did not suffer from mitral annular calcification, Ms. Panoussi did not provide the actual tape of that echocardiogram. Thus, Dr. Wang and Dr. Vigilante were not able to review it.

Claimant further argues that the fact that she had mitral valve repair, rather than replacement, surgery is evidence that she did not have mitral annular calcification. Dr. Salmon's own statement undermines this argument. Dr. Salmon opined that "calcification of the mitral annulus renders mitral valve repair difficult and replacement surgery is typically performed in cases involving mitral annular calcification." (Emphasis added.) Dr. Wang confirmed that patients with mitral annular calcification undergo repair surgery routinely and that she has even consulted on such procedures. Thus, it is not reasonable to infer that simply because Ms. Panoussi underwent mitral valve repair surgery she did not have mitral annular calcification.

For the foregoing reasons, we conclude that Ms. Panoussi has not met her burden of proving that there is a reasonable medical basis for finding that she did not have mitral annular calcification. Therefore, we will affirm the Trust's denial of Ms. Panoussi's claim for Matrix A-1 Benefits.